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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/720,985

11/24/2003

Peter Michel

11623/US/2

3362

74307

7590

10/13/2009

Dorsey & Whitney LLP
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EXAMINER

BERDICHEVSKY, AARTI

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

10/13/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/720,985	Applicant(s) MICHEL, PETER	
	Examiner Aarti Bhatia Berdichevsky	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-41, 43 and 45-51 is/are pending in the application.
- 4a) Of the above claim(s) 13-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40, 41, 43, and 45-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This is the fourth Office Action based on the 10/720,985 application filed on 11/24/2003. Claims 1-41, 43, and 45-51, as amended on 8/04/2009, are currently pending and have been considered below.

Response to Amendment

Claim Rejections - 35 USC § 102

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 40, 41, 43, 47, 49 and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,380,279 to Schmidt.

Schmidt discloses a method for administering an injectable product from a reservoir, the method comprising: providing a first volume (27) and a second volume (37), wherein the volumes are adapted to contain a medical liquid fluid; placing the volumes in fluid communication (28); and decreasing the volume of the first volume, thereby causing the amount of fluid in the second volume to increase (see figure 3), wherein the first volume is decreased by urging a first piston (31) in a first direction (up) against the first volume via a spring (36); and wherein the increasing second volume causes the second volume to exert a compression force on a second piston (41) that drives the second piston in a second direction (down--which is opposite from the first direction), which causes the administration of injectable product from the reservoir (see figure 4).

Claim Rejections - 35 USC § 103

3. Claims 45, 46, 48, and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt.

Schmidt teaches the method of claim 40, but fails to teach the differences in the area of contact between the piston and fluid volume, as well as a third piston, and that the working fluid is an oil.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the injector of Schmidt with various areas of contact between the piston and fluid volumes to arrive at the desired fluid pressure differential, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Further, it would have been obvious to include an additional piston in the drive scheme of the injector to add additional control over the delivery of the desired drug, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Further, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use oil as the working fluid, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Response to Arguments

4. Applicant's arguments filed 8/04/2009 have been fully considered but they are not persuasive.

5. The Applicant states that claim 40 (and 51) requires the second volume to increase to cause the release of the product, and argues that Schmidt fails to disclose this feature. The Examiner disagrees. Schmidt teaches all the required limitations of claim 40 (and 51). Schmidt teaches that the decrease of the first volume causes the second volume to increase. This eventually will cause the administration of the injectable product from the reservoir. The claim does not require that the increase of the second volume to directly force the product release. The Examiner finds that although there is a decrease in the second volume after there is an increase in the second volume, the increase in the second volume will cause the product to release, eventually. The Applicant argues that the same "second volume" must be used consistently throughout the rejection. The Examiner fully agrees, and is only claiming 37 of Schmidt to be the second volume. The Examiner appreciates the numerous structural details between the devices of Schmidt and the present application, however, these features have not been claimed in the current claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aarti Bhatia Berdichevsky whose telephone number is 571-270-5033. The examiner can normally be reached M-Th 8 AM to 6 PM.

Art Unit: 3763

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aarti Bhatia Berdichevsky/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763